K130224
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iCT

IMRIS

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

JUL 18 2013

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Date Prepared: May 15, 2013

Device Name

Trade Name: iCT
Common Name: System, X-ray, Tomography, Computed (JAK)
Classification Name: Computed Tomography X-ray System (21 CFR §892.1750)

Predicate Devices:

510(k)	Decision Date	Device Name	Manufacturer
K081022	Jun 2, 2008	SOMATOM Definition, Model AS/AS+	Siemens Medical Solutions USA, Inc.
K032475	Nov 10, 2003	SOMATON Computed Tomography X-Ray Systems Sliding Gantry Option	Siemens Medical Solutions USA, Inc.

Device Description:

iCT is a whole body x-ray computed tomography (CT) scanner. It combines a standard CT gantry with a ceiling mounted suspension and drive mechanism to move the gantry horizontally during image acquisition. The standard CT gantry features a continuously rotating tub-detector system and functions according to the fan beam principle. The ceiling mounted suspension and drive mechanism allows iCT to be moved along rails for storage or to share the iCT between multiple rooms. The ceiling mounted system also provides precise horizontal movement that is integrated with the CT scan control. During image acquisition, the iCT drive mechanism translates the CT gantry while the patient table remains stationary. Moving the gantry allows the patient to remain stationary instead of translating the patient relative to the gantry as is required with fixed gantry systems. iCT may be used with commercially available patient tables, including surgical tables, that meet the appropriate size and x-ray transmission characteristic requirements.

iCT leverages the previously cleared SOMATOM Definition, Model AS/AS+ (K081022) gantry, power supply and operator console components, including the syngo software platform and compatible syngo applications. iCT produces CT images in DICOM format. The syngo platform is able to run optional post-processing applications.

Intended Use:

The iCT device with sliding gantry is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral plane: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the sliding gantry).

Comparison with Predicate Devices:

iCT is substantially equivalent to the currently cleared and marketed SOMATOM Definition, Model AS/AS+ (K081022) when used with the optional sliding gantry package cleared earlier under SOMATON Computed Tomography X-Ray Systems Sliding Gantry Option (K032475) by Siemens Medical Solutions USA, Inc. The predicate SOMATOM Definition, Model AS/AS+ is a standard CT system. As a SOMATOM family CT scanner it can be used with the SOMATON Computed Tomography X-Ray Systems Sliding Gantry Option.

The SOMATOM Definition, Model AS/AS+ with Sliding Gantry Option provides a fully functional CT scanner that moves the CT gantry along rails mounted in the floor. This allows the patient to remain stationary on a fixed table as the gantry moves horizontally during image acquisition.

iCT provides a fully functional CT scanner that moves the CT gantry suspended from rails mounted in the ceiling. It also uses the horizontal motion of the gantry while the patient remains stationary on a table during image acquisition.

iCT uses the SOMATOM Definition, Model AS/AS+ gantry, power supply and operator workspace components. Therefore, the x-ray characteristics and scan interfaces are the same. It acquires images using the same method for incorporating gantry translation into scan control movement as the cleared Sliding Gantry Option. The primary difference between the predicates and iCT is that iCT travels on ceiling rails instead of floor rails. These differences have been identified and assessed in risk management and are addressed by recognized standards and the included testing.

Summary of Studies:

iCT performance has been evaluated in verification and validation to ensure the ceiling railing system maintains the performance of the contained SOMATOM Definition, Model AS/AS+ system components. Risk Management has been applied to identify, mitigate and test the distinctions between iCT and the SOMATOM Definition, Model AS/AS+ with the sliding gantry package. Image quality testing based on high precision phantoms was provided in this submission to demonstrate substantial equivalence with the predicate. iCT has been tested to perform to the same image quality, z-axis accuracy and gantry stability specifications as the SOMATOM Definition, Model AS/AS+ with the sliding gantry package. iCT has also been tested to conform to applicable product safety standards. iCT meets the applicable

requirements of the Federal performance standards for ionizing radiation emitting products defined in 21 CFR §§1020.30 and 1020.33 for CT systems. It conforms to the applicable International Electrotechnical Commission (IEC) 60601 family of standards, including applicable collateral and particulars, for medical devices and CT systems. iCT complies with NEMA XR-25, Computed Tomography Dose Check.

The iCT system uses a previously cleared CT system with cleared moving gantry option as a base, and the major modification to the predicate is the integrate hardware that allow for the system to be mounted on the ceiling instead of the floor. Because the major software and hardware components in the imaging chain are unmodified from the predicate, sample clinical images are unnecessary to support substantial equivalence in this case and instead testing relied on laboratory studies.

iCT verification and validation results support a determination of substantial equivalence.

Additional Information:

Substantial equivalence was evaluated based on software documentation for a Moderate Level of Concern device.

Conclusion:

iCT is substantially equivalent to the currently cleared and marketed SOMATOM Definition, Model AS/AS+ (K081022) when used with the optional sliding gantry package, SOMATON Computed Tomography X-Ray Systems Sliding Gantry Option (K032475). iCT has been successfully tested to operate within the same performance and image quality specifications as the currently cleared and marketed SOMATOM Definition, Model AS/AS+. iCT has been evaluated to conform to applicable product safety standards that have been recognized to address known CT risks. iCT is substantially equivalent to the predicate based on the included studies and analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

IMRIS, Inc.
% Mr. Daniel Biank
Director, Regulatory Affairs
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CANADA

Re: K130224
Trade/Device Name: iCT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 16, 2013
Received: May 20, 2013

Dear Mr. Biank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

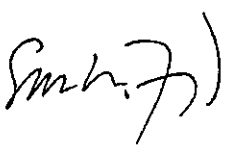
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130224

Device Name: iCT

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The iCT device with sliding gantry is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130224